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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1255]

Electronic Submission Process for Requesting Export Certificates From the Center for Devices and Radiological Health; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an electronic submission process for requesting export certificates for products regulated by FDA's Center for Devices and Radiological Health (CDRH). The electronic process will help fulfill both the legislative and application time processing requirements set out by the FDA Export Reform and Enhancement Act of 1996 and the terms of clearance of the Office of Management and Budget approval (OMB control number 0910-0498) of the Form FDA 3613 series. The new eSubmitter process will compliment the current paper-based process.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. How eSubmitter Impacts FDA's Current Process

FDA currently accepts requests for export certificates submitted by mail. This process will remain in place and would be augmented by the new eSubmitter process.

For general user assistance, contact the Center for Devices and Radiological Health (CDRH), Division of Small Manufacturers, International and Consumer Assistance (DSMICA) by telephone: 1-800-638-2041 or 301-796-7100; or by email: dsmica@fda.hhs.gov.

You can find information about FDA's Electronic Submissions Gateway online at: http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm. Email questions about the system to FDA's Electronic Submissions Gateway Help Desk: esgreg@gnsi.com.

II. Background on the Electronic Submission of Requests for Export Certificates

FDA introduces an electronic option for submitting requests for export certificates of devices regulated by CDRH as a voluntary alternative to paper submissions. With electronic submissions, CDRH can more readily receive and process the export requests.

The electronic process will be introduced in two phases. In the first phase of operation, the CDRH Export Certification Application and Tracking System (CECATS) will be made available to industry for the electronic submission of requests for export certificates.

CECATS is a Web-based application used by FDA's CDRH to process, manage, and administer certificates for the export of medical devices. CDRH will be implementing the electronic submission and review process. Industry will have an option to submit electronically or via the paper process. CECATS will be accessible through the FDA Unified Registration and Listing System (FURLS). A firm must have a FURLS account to access CECATS.

The CECATS module is a part of the FURLS application within the FDA Industry Systems Portal utilized to automatically issue the certificate to U.S. medical device manufacturers/distributors who wish to export their medical devices to foreign countries.

CECATS will help fulfill both the legislative and application time processing requirements set out by the FDA Export Reform and Enhancement Act of 1996 (Public Law 104-134) and the terms of clearance of the OMB approval of the Form FDA 3613 series.

CECATS will provide industry the option of submitting export requests electronically. Electronic submission will automate many of the steps that both industry and CDRH must perform to submit and process export certificates. The advantages to industry will be:

- Certificate processing time will be greatly reduced;
- Automated real-time validation will eliminate the need to return submissions; and
- Industry will receive real-time updates on the status of their requests via the Web.

In early 2013, FDA will implement phase two for the remainder of the export certification, notification, and permit requests listed as follows:

- Certificates of Exportability (sections 801(e)(1) and 802 of the FD&C Act);
- Non-Clinical Research Use Only Certificate;
- Simple Notifications (section 802(g) of the FD&C Act); and
- Export Permit Letter (section 801(e)(2) of the FD&C Act).

Upon full implementation in 2013, industry will be able to submit all export requests electronically. This is a "win" for both industry and CDRH as it will allow us to process all export requests more efficiently and expeditiously. CDRH is developing webinars and will hold online training sessions with industry on how to access and use CECATS. A schedule and detailed instructions will be sent to industry and posted to our Web site at:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ucm050521.htm#ref when they become available.

Evaluation of the electronic submission process will be conducted periodically to further enhance both user interface and data collection needs as they become known to FDA. Electronic submissions of requests for export certificates will remain voluntary at this time.

The printable forms can be viewed at the following links:

- Form FDA 3613: Supplementary Information Certificate for Foreign Government Requests: http://inside.fda.gov:9003/ucm/groups/insidefda-public/@inside-adm-forms/documents/form/ucm012794.pdf;
- Form FDA 3613a: Supplementary Information Certificate of Exportability Requests: http://inside.fda.gov:9003/ucm/groups/insidefda-public/@inside-adm-forms/documents/form/ucm012795.pdf;
- Form FDA 3613c: Supplementary Information Non-Clinical Research Use Only Certificate: http://inside.fda.gov:9003/ucm/groups/insidefda-public/@inside-adm-forms/documents/form/ucm012797.pdf.

III. What Happens When the New eSubmitter Process for Requesting Export Certificates is Implemented?

Implementation of the eSubmitter process will supplement the ability to request export certificates from CDRH via paper. The new Web-based application (available at: https://www.access.fda.gov/oaa/index.jsp) uses your existing FURLS account information. The Web site provides an alternative to the paper request process by enabling online submission of export certificate applications.

IV. Paperwork Reduction Act of 1995

This document refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in CECATS and Forms FDA 3613, 3613a, and 3613c have been approved under OMB control number 0910-0498.

Dated: January 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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